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(71) Applicant (for all designated States except US): AKTIEBO-

(71) Applicant (for all designated States except US): AKTIEBO-LAGET ASTRA [SE/SE]; S-151 85 Södertälje (SE).

(72) Inventors; and
(75) Inventors/Applicants (for US only): CHRISTOFFERSSON,
Rolf [SE/SE]; Norra Rudbecksgatan 19, S-752 36 Uppsala
(SE). ANDERSSON, Birger [SE/SE]; Utlandagatan 16, S-412 61 Göteborg (SE).

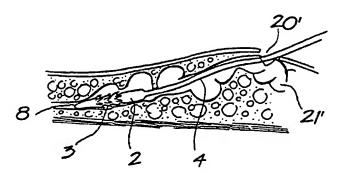
(74) Agent: KALLING, Sven; AB Astra, Patent Dept., S-151 85 Södertälje (SE).

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(54) Title: DEVICE FOR THE EXTIRPATION OF VARICOSE VEINS



(57) Abstract

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The invention relates to a device for the local extirpation of varicose veins to be inserted into a vein to be removed. The device (1) comprises a head part (2, 32, 52, 72, 92) comprising a main body provided with barbs (3, 33, 53, 73, 73', 93) and a guiding tip (8, 98, 78) facilitating the insertion of the device (1) into the vein, the barbs (3, 33, 53, 73, 73', 93) being oriented backwards relative to the direction of insertion of the device (1) so that the head part (2, 32, 52, 72, 92) can be inserted into said vein without being impeded by said barbs (3, 33, 53, 73, 73', 93), said barbs (3, 33, 53, 73, 73', 93) having a length and being at an angle relative to the longitudinal direction of the head part (2, 32, 52, 72, 92) in the operative position of the barbs (3, 33, 53, 73, 73', 93) which are sufficient to ensure that a vein, for which the device (1) is dimensioned, is gripped firmly by said barbs when said head is pulled out from said vein, a flexible actuating means (4, 34, 54, 74, 74', 94) being attached to said head.

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#### DEVICE FOR THE EXTIRPATION OF VARICOSE VEINS

#### Technical field of the invention

5 The present invention relates to a device for local extirpation of varicose veins which is to be inserted into the vein to be removed. The invention also relates to a method for local extirpation of varicose veins.

#### 10 Background of the invention

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Varicose veins are superficial, subcutaneous veins that are pathologically enlarged and tortuous due to dysfunctional valves in the perforating veins, the saphenous veins or in the tributaries (branches) thereto. Varicose veins is a common problem which causes heaviness, stiffness and fatigue in the legs as well as bluish/purple bulges which are undesirable from a cosmetic point of view. Varicose veins which are left untreated may cause severe pain, excema and leg ulcers.

The methods for treating varicose veins mainly comprise surgical removal of the veins or methods which involve the chemical or surgical destruction of the endothelium which causes obstruction of the affected vessels. The main surgical methods are stripping and local extirpation.

The stripping technique, which normally is used on the saphenous veins, consists of passing a probe through an incision in the skin and along the entire length of the vein. The probe is then passed out through a second incision in the skin and provided with a head, whereafter the entire vein is removed together with the probe. An example of a device for this purpose is disclosed in US-

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A-4,528,982.

US-A-5,011,489 discloses a device for the surgical destruction of the endothelium in the saphenous veins.

5 This device comprises a probe-like element which is provided with one or several conical head members. The conical surfaces of the head members are substantially covered with barbs serving as cutting or scraping elements for removing the endothelium from the inside of the saphenous veins when the device is passed through the vein.

Local extirpation can be defined as the removal of tributaries and/or smaller parts of the saphenous veins through incisions in the skin through which the vein is pulled out.

In the conventional techniques used for local extirpation, one or several incisions are made over each varicose vein. One end of the vein to be removed is grasped and stretched with a surgical clamp. The vein is freed as far as possible using a dissecting scissors or a device specially designed for this purpose, such as the device disclosed in GB-A-2,195,540. The vein is torn at the distal end and does not have to be ligated.

In this way vein segments having a length of about 5 cm can be removed. The disadvantages of this method are that only short lengths of the vessel are removed, that numerous incisions will have to be made, that the dissection involves risks of damage to nerves and small arteries, causing haematomas, and that the operation is time-consuming.

35 Roshledy y chirurgi, 56, 1977 by E. Luza (largely

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corresponding to the Czech patent specification 172067 in the name of Luza) suggests a device for removing very small varicose veins and superficial telangiectasias, that is vascular malformations consisting of dilated capillaries, arterioles and venules. The device consists of a spiky needle made of stainless steel by the means of which the telangiectasia are shredded. This device can only be used for small vessels and involve a risk of damage to the surrounding tissues.

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Czech patent specifications 169617 and 165586, also in the name of Luza, suggest devices for the local extirpations of varicose veins comprising rigid cutting and stabbing implements by the means of which the meanders of the veins are pierced and the veins then are removed. In view of the extensive use of sharp points and cutting edges, again there is a risk of damage to the surrounding tissue.

#### 20 Short description of the inventive concept

The object of the present invention is to provide a device for the local extirpation of varicose veins which will remove the veins whilst minimizing the damage to the surrounding tissue and vessels, at the same time providing a possibility of removing longer segments of the veins, thus reducing the number of incisions. This will in turn give a better cosmetic result and will reduce the time needed for the operation. When more of the affected veins can be removed, the risk for a recurrence and a subsequent reoperation of the condition will be reduced.

A further object of the invention is to provide a device which can be manufactured in a way which is sufficiently

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cheap and simple to allow the device to be used as a disposable device, i. e. a device that, although the device normally is used to perform several extirpations on one and the same patient during one and the same operation seance, can be discarded after the completion of the operation seance.

According to the invention the above objects are achieved in that said device comprises a head part comprising a main body provided with barbs and a guiding tip facilitating the insertion of the device into the vein, the barbs being oriented backwards relative to the direction of insertion of the device so that the head can be inserted into said vein without being impeded by said barbs, said barbs having a length and being at an angle relative to the longitudinal direction of the head in the operative position of the barbs which are sufficient to ensure that a vein, for which the device is dimensioned, is gripped firmly by said barbs when said head is pulled backwards, a flexible, actuating means being attached to said head.

The above objects are also achieved by a method for the local extirpation of varicose veins as set forth in the appended claim 15.

Preferred embodiments are set forth in the dependent claims.

#### 30 Short description of the appended drawings

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Fig 1 shows the general design of a device according to the invention having a head part provided with barbs,

35 Fig 2 illustrates a conventional operation for local

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extirpation of varicose veins,

Fig 3 illustrates local extirpation of varicose veins by using a device according to the invention,

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Figs 4 - 10 illustrate different embodiments of the head part of the device in fig 1,

Figs 11 - 13 illustrate alternative embodiments of the head part of the device in which the barbs are placed on resilient arms,

Fig 16 illustrates a head part with retractable barbs.

Detailed description of preferred embodiments of the invention

As shown in Fig 1, a first embodiment of the invention is generally designated with the reference sign 1 and comprises two parts, namely a generally cylindrical head part 2 which is provided with barbs or flanges 3 and a flexible, resilient, semi-rigid wire 4, which is provided with a handle 5.

The entire device 1, apart from the handle is preferably molded in one piece of a polymeric material, for instance polycarbonate, polyamide, polyoximethylene or similar which results in a device having a flexibility well adapted to allow the device to be pushed all the way through the tortuous relative to the walls of the vessel.

The barbs are arranged in rows on the head part and at least one barb-free groove 6 is arranged between two adjacent rows of barbs, said groove preferably being oriented in the longitudinal direction of the device. The

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tip of the device is provided with a rounded extension 8 serving to guide the device along the vein when the device is inserted into the vein. The extension may by angled, for instance at an angle of 45°, relative to the longitudinal extent of the head part in order to facilitate the insertion of the device into the meanders of the varicose vein. An example of an angled guide part is shown in Figs 11 - 15. The extension may of course be designed in such a way, for instance by including a bendable wire, that the surgeon can bend the extension to a desired angle. The device 1 may have a total length of about 20 cm and the diameter of the wire 4 may be 1.5 mm or thereabout. In order to reinforce the wire, a thin wire of stainless steel may be molded into or located in the wire. A non-limiting example of a suitable semirigidity, resilience and flexibility may for instance be defined by means of a wire having a circular crosssection with a diameter of 1.7 mm which is made of a polycarbonate commercially available under the trade name Makrolon 3208. The device will be made with heads having different diameters depending on the size range of the veins in which the device is to be used. A typical diameter range may for instance be 3 - 7 mm. The height of the barbs preferably is proportional to the diameter of the head part.

The conventional technique for operating is shown in Fig 2, which illustrates how a varicose vein 21 is grasped through an incision 20 by means of a surgical clamp 22, the vein 21 being freed from the surrounding tissue 24 by means of dissecting scissors 23.

In contrast to this, the device according to the invention is used as follows:

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Before the operation the surgeon carefully marks the extent of the varicose veins on the skin of the patient. As illustrated in Fig 3, the operation starts with a incision 20' in the skin over the varicose vein 21'. The varicose vein is opened and the head part 2 of the device is pushed into the varicose vein and guided through the meanders with the help of the guiding tip 8, until the device cannot be pushed any further. The length and flexibility of the wire 4 makes it possible to insert the device a distance up to 15 - 20 cm (i. e. the entire length of the device) from the incision in the skin. By means of the barbs 3 of the head part 2, the inside of the vessel will be gripped when the device is pulled backwards. The foremost barbs will cut into the vessel wall when the device is pulled backwards, thereby weakening the wall, resulting in that the vessel easily is torn in this place. Normally the vessel will be turned inside out during the outward movement and the vessel consequently will be withdrawn together with the device. During this movement the surrounding tissue thus will be protected from the barbs by at least two layers of vessel. If the chosen size of the head happens to be too large in relation to the diameter of the vessel to be removed (the number of sizes being limited), it may happen that the vessel simply is curled up against the head. In this case the surrounding tissue will still be protected from the barbs by one layer of the vessel wall and to some extent by the folds which may serve as distance elements or spacers.

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The above technique may be described as "transluminal stripping". In contrast to the conventional techniques for local extirpation, the varicose veins thus never have to be freed from the surrounding tissue since the surgeon always works from inside the vessel.

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The surgeon then removes the vessel from the device by cutting along the head part 2 in the groove 6 between two rows of barbs 3. The device is now ready for renewed use. One and the same instrument thus can be used for several local extirpations in one and the same patient during one and the same operation.

With the device according to the present invention it is possible to remove several varicose veins in a shorter operation time than with the current, manual dissection. In view of the length of the device a smaller number of incisions have to be made in the skin, with a smaller number of disfiguring scars. Since several varicose veins can be removed at a first operation, the symptoms will be relieved more efficiently and the need for a reoperation will be reduced. Since the varicose veins are removed transluminally, the risk for vascular and neural damage is reduced. As a result of the shorter operation time and the minimized risk for damage to the surrounding tissue, the post-operative swelling and pain as well as the risk for infection decreases.

Figs 4 - 10 illustrate different ways of designing the head part described above.

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In Fig 4, the head part 2 is moulded in one piece in the form of a cylinder provided with a plurality of longitudinal grooves 6, each pair of grooves defining an intermediate ridge or spline 10. The barbs 3 are formed after the moulding process by cuts made in the splines 10 by means of a cutting instrument. The rounded extension 8 is designed in the form of a cylindrical extension ending in a spherical part 9. Fig 5 shows a section of the head part in Fig 4 taken along the line V-V.

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Figs 6 and 7 illustrate a design rather similar to the design in Figs 4 and 5, but which is particularly suitable for permitting the moulding of the head part 2, including the barbs 3, in one single step in a standard moulding technique for moulding undercut parts. Fig 7 is a section along the line VI-VI in Fig 6.

Both the above embodiments are preferably moulded integrally with an actuating wire 4.

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Figs 8 - 10 illustrate an alternative way of designing the head part. In Fig 8, the barbs 33 are formed by means of a plurality of frusto-conical sleeves 41 with a central bore 42 which are threaded onto a head part 32 against a stop 40. The larger circular (bottom) surface 45 of the sleeves 41 is slightly undercut. The outer conical surface of the sleeves 41 are provided with longitudinally oriented grooves delimiting splines 46 which form barbs 33 at their intersection with the larger bottom surface 45. When the sleeves have been placed on the head part 32, a stop (not shown) is formed in the head part in front of the sleeves. The stop may of course also be attached to the head part by glueing, welding or similar. The stop may be designed with a spherical shape in front of which a rounded extension, for instance in accordance with the extension 8, 9 described above in connection with the embodiments according to 4 - 7. In one embodiment the sleeves 41 are freely rotatable against this spherical stop, which has the advantage that the trauma in the veins will be minimized if the head part 32 is rotated to facilitate the insertion of the head part into the vein since the sleeves will not rotate relative to the vein wall. In another embodiment one end of each sleeve may be provided with a lug 43 fitting into a recess 44 provided in the other end of the sleeve to

lock the sleeves against rotation and to orient the grooves 36 correctly to form one continuous groove from one end of the main body to the other. The head part is preferably moulded in one part with an actuating means or wire 34.

Figs 9 and 10 illustrate another embodiment in which the conical sleeve-like elements are formed from planar, star-shaped plates 60 with a central hole 61, with a plurality of points 63 and with a plurality of 10 diametrically oriented cut-outs 62, the length of a diameter of the hole added to the lengths of two cut-outs largely corresponding to the diameter of a head part 52. A plan view of the plate 60 is shown in Fig 10 and a section along the line IX - IX is shown in Fig 9 together 15 with a side view of the head part with mounted plates. The edge of the plate may be, but as illustrated, does not have to be perpendicular to the planar surfaces of the plate. When the head part part 52 is forced through the hole 61, the central part of the plate 60 will be 20 elastically deformed, i. e. twisted about 90 degrees, to form a ring around the head part, the points 63 forming conically flaring barbs 53 extending from said ring. The material and dimensions of the plate will be chosen to ensure that the ring is securely fixed against the head 25 part 52. If necessary, the bond between sleeve and head part can be improved, for instance by ultrasonic welding. The head part 52 may be an end part of an actuating wire 54.

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Figs 11 - 15 show three embodiments which differ from the embodiments described above in that the barbs are located on resilient arms. In all three embodiments a first or front end of said arms 81 are resiliently and hingedly attached to a spherical part 80 at the forward end of the

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head part 72 and the barbs may be formed by cuts 82 in the arms, the cuts being opened when the the ends of the arms are bent towards the head part 72, see for instance Fig 15. Fig 12 is a section taken along line XII - XII in Fig 11. As mentioned above, all the three embodiments also illustrate an example of a curved design of the guide part 78, 79 in dashed lines.

In these embodiments, the arms will define the rows of barbs referred to above and the free spaces between the arms as the grooves between the rows discussed in connection with the embodiments described above.

In the embodiment according to Fig 11 the second or rear end of the arms 81 are free which means that the arms will expand freely against the inner wall of the veins when the barbs 73 engage the wall during the withdrawal of the head part 72, thus increasing the engagement of the barbs. The main body of the head part may be a part of an actuating wire 74.

Sometimes it may be desirable to limit the expansion of the arms 81 against the walls of the veins. One way of doing this is to provide the rear ends of the arms 81 with a shape which has been curved outwardly and over which a resilient ring 83 can be slipped, thus limiting the movement of the arms, see Fig 13.

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Another way is illustrated in Figs 14 and 15, in which the rear end of the arms 81 are attached to the outside of an actuating member 74' in the form of a hollow tube, for instance by means of attachment lugs 86 glued or welded into corresponding holes in the tube 84. One end of the head part 72 is freely movable in the tube 74'. In a preferred embodiment the head part is provided with

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stop means 85 which limit the distance the head part 72 can be moved into the tube 74'. In a variation of this embodiment, a thin wire 87 (indicated with a dashed line), for instance made of stainless steel, is moulded into the head part 72. The wire 87 runs through the entire length of the tube 74' and ends outside the free end of the tube in a handle (not shown). By these means the arms 81 can be made to expand arcuately forcibly by pulling on the wire 87 whilst holding the tube 74'. The expansion will be limited by the stop means 85 or, optionally, by stop means arranged in said handle. In this embodiment, the cuts by which means the barbs are formed may be left virtually closed during the insertion of the head part, the cuts opening to form barbs when the arms are expanded arcuately against the inside walls of the vein to be removed. In a sense, this embodiment thus can be said to have retractable barbs.

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It should be noted that the embodiments according to Figs 11 - 15 also can have moulded barbs, see for instance the barbs 73' in Figs 11, 12, 13 and 14.

The embodiments according to Figs 11 - 15 may to some extent be more difficult to manufacture than the embodiments described above, but their main advantage is that they are more adaptable to the size of the vein to be removed.

Fig 16, finally illustrates an embodiment of the device
which is provided with retractable barbs. The device
comprises a head part 92 and a guide tip 98, only a part
thereof being shown. A wire 101 is moulded into a block
105 which is glued or welded to the head part 92. The
wire 101 is located inside a tube 94 serving as the
35 actuating means together with the wire 101. The head part

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also comprises barbs 93 being formed by a plurality of crescent-shaped elements 104 (in this case four) moulded integrally with a respective ring 103. A plurality of the rings 103 (in this case three) are arranged on the head part 92 and are separated by sleeve-shaped spacer elements 102. The inner diameter of the spacers 102 is somewhat larger than the outer diameter of the tube 94. The barbs 93 are located in rows along the outside of the head part. The rings and the spacers are attached to each other and to the front part of the head part by means of narrow welds extending longitudinally between the barbs 93. Since the rings, apart from the welds, are free relative to the spacers, the crescents can rotate to some extent against a torsional bias exerted from the rings. Each spacer element is provided with slits allowing the rotation of the crescents. In the normal position, one end of the crescents 104 extend into the interior of the head part 92, the other end extending outwardly from the exterior of the head part 92, thus forming the barbs 93. The barbs 93 can however be made to retract by pushing the tube 94 into the interior of the head part 92 all the way past the rings 103. When the end of the tube passes each ring, the inner end of the crescents will be forced to swing up into a respective slit in the spacers and the outer end of the crescents, i. e. the barbs, will swing down into a respective slit. In this way the barbs will be retracted. When the tube is pulled out from the interior of the head part, the barbs will swing out again under the torsional bias from the rings.

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### Possible modifications of the invention

The invention may of course be modified in many ways within the scope of the appended claims.

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For instance, in the embodiments illustrated above the barbs have been illustrated as having rear surfaces which are undercut, i. e. surfaces that form an angle with the longitudinal direction of the device which is smaller than 90°. It is however conceivable to provide an angle that is equal to or slightly larger than 90° as long as the barb can fulfil its function as a barb and grip the inside of the vein firmly.

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#### CLAIMS

- 1. Device for the local extirpation of varicose veins to be inserted into a vein to be removed,
- 5 characterized in that said device (1) comprises a head part (2, 32, 52, 72, 92) comprising a main body provided with barbs (3, 33, 53, 73, 73', 93) and a guiding tip (8, 98, 78) facilitating the insertion of the device (1) into the vein, the barbs (3, 33, 53,
- 73, 73', 93) being oriented backwards relative to the direction of insertion of the device (1) so that the head part (2, 32, 52, 72, 92) can be inserted into said vein without being impeded by said barbs (3, 33, 53, 73', 93), said barbs (3, 33, 53, 73', 93) having a length
- and being at an angle relative to the longitudinal direction of the head part (2, 32, 52, 72, 92) in the operative position of the barbs (3, 33, 53, 73, 73', 93) which are sufficient to ensure that a vein, for which the device (1) is dimensioned, is gripped firmly by said
- 20 barbs when said head is pulled out from said vein, a flexible actuating means (4, 34, 54, 74, 74', 94) being attached to said head.
  - 2. Device according to claim 1,
- 25 characterized in that said barbs (3, 33, 53, 73, 73', 93) are arranged in rows separated by at least one groove (6, 36,) extending from one end of said main body to the other end.
- 30 3. Device according to claim 2, c h a r a c t e r i z e d in that said rows of barbs (3, 33, 53, 73, 73', 93) and said grooves (6, 36) are longitudinally oriented.
- 35 4. Device according to any one of the preceding claims,

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c h a r a c t e r i z e d in that said main body is cylindrical and that said barbs (3) are formed directly on the body.

- 5 5. Device according to claim 2, c h a r a c t e r i z e d in that said barbs (33, 53) are formed by sleeve-like elements (41, 60) provided with a central bore (42, 61) which are threaded onto a head part (32, 52) which preferably is cylindrical, said 10 sleeve-like elements having a substantially conical shape in their mounted state.
- 6. Device according to claim 5,
  c h a r a c t e r i z e d in that said sleeve-like
  15 elements (41) are frusto-conical and have a central bore (42), said elements having a larger, undercut circular surface (45), a smaller circular surface and a outer, conical surface delimited by said circular surfaces, said outer, conical surface being provided with splines (46),
  20 the intersection of said splines (46) with the larger circular surface forming said barbs (33).
- 7. Device according to claim 5,
   c h a r a c t e r i z e d in that said elements (60),
   25 which are planar before mounting, comprise a central hole (61), the dimensions of said hole (61) being smaller than the dimensions of a crossection of said main body, said planar elements (60) being twisted to a substantially conical shape when the elements are forced onto the main body.
  - 8. Device according to claim 7,
    c h a r a c t e r i z e d in that said elements are
    star-shaped in their planar state.

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9. Device according to claim 2, c h a r a c t e r i z e d in that said head part (72) comprises resilient arms (81) having two ends, said barbs (73, 73') being located on said arms (81) and preferably being formed by cuts (82) in said arms (81), a first end of said arms being attached to said main body at a first or front end thereof.

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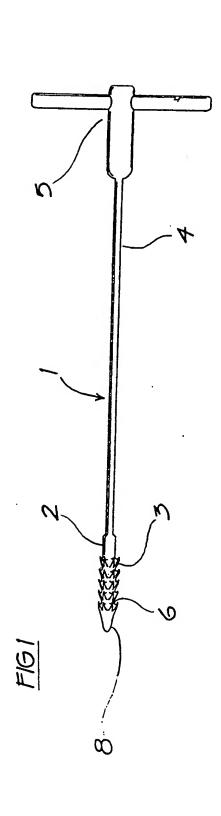
- 10. Device according to claim 9, c h a r a c t e r i z e d in that said arms (81) are arcuate, a second end of said resilient arms (81) being biased against said main body by means of a ring (83).
- 11. Device according to claim 9,

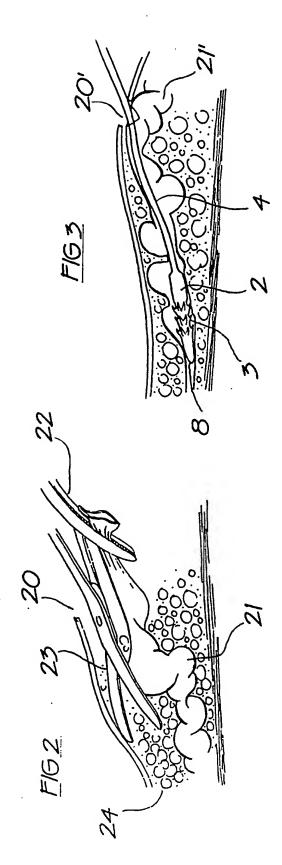
  15 characterized in that said second end of said arms (81) is attached to said actuating means (84), said second end of said main body being freely movable relative to said actuating means (84).
- 20 12. Device according to claim 11, characterized in that said actuating means is in the form of a tube (84), said second end of said main body being movable in said tube.
- 25 13. Device according to claim 11, c h a r a c t e r i z e d in that an actuating wire (87) extending through said tube (84) is attached to said second end of said main body, a pulling action on said wire (87) causing said arms (81) to expand.
  - 14. Device according to any one of claims 1 3, c h a r a c t e r i z e d in that said actuating means is in the form of a tube (94) slideable on a wire (101), said main body being in the form of a hollow cylinder, having an inner diameter slightly larger than the outer

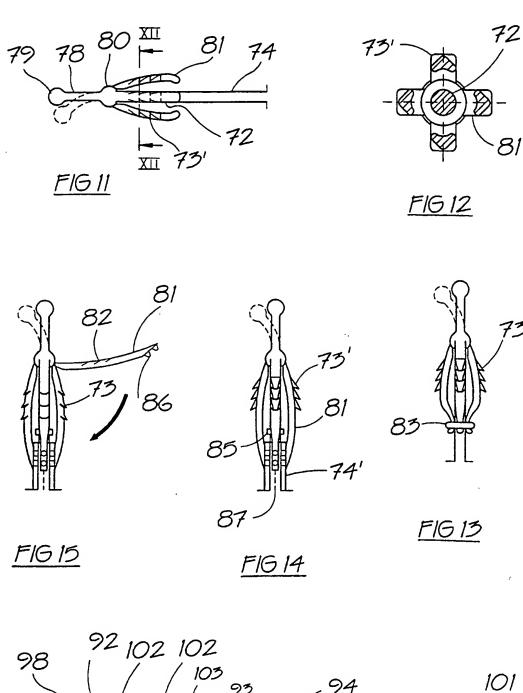
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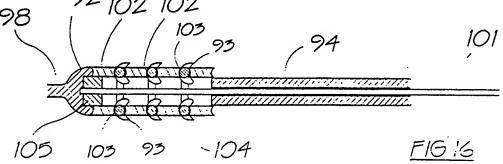
diameter of said tube (94), said wire (101) extending through the interior of said cylinder and being attached to said cylinder at the far or front edge thereof, said cylinder being provided with elongated barb elements (104) located in through slits in the cylinder surface, said barb elements (104) being rotatably attached to said cylinder and resiliently biased to a position in which one end of said barb elements extends outwardly from said cylinder surface forming barb means (93) and one end of 10 said barb elements extends inwardly from said cylinder surface, a movement of said tube (94) along said wire (94) into the interior of said cylinder forcing the inner end of said elements (104) to swing into said slits and consequently also swinging the outer ends (93) into said 15 slits, the barb means (93) in this way being retracted.

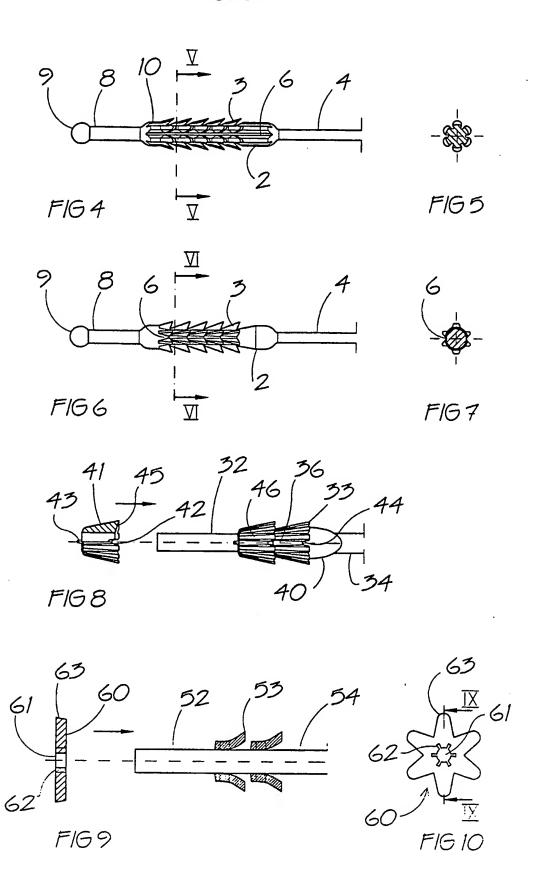
- 15. Method for the local extirpation of varicose veins, c h a r a c t e r i z e d by the following steps:
- a) insertion of a device according to one or several of
- 20 claims 1 14 into a varicose vein until the head part of the device attaches itself to the vessel;
  - b) pulling the device out of the vessel, the vessel normally being inverted and being withdrawn together with the device;
- 25 c) removal of the vessel from the device by cutting the vessel along a groove (6) on the head (2) of the device; and
  - c) possibly repeating the steps a) to c) for the removal of additional varicose veins in the same patient.











### INTERNATIONAL SEARCH REPORT

International application No. PCT/SE 94/00217

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A. CLAS	SIFICATION OF SUBJECT MATTER		
	A61B 17/00, A61B 17/32 to International Patent Classification (IPC) or to both r	ational classification and IPC	
	DS SEARCHED		
IPC 5:	locumentation searched (classification system followed b	y classification symbols)	
Documenta	tion searched other than minimum documentation to th	e extent that such documents are included	in the fields searched
SE,DK,F	I,NO classes as above		
Electronic o	lata base consulted during the international search (nam	e of data base and, where practicable, searc	ch terms used)
C. DOCI	JMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where ap	propriate, of the relevant passages	Relevant to claim No.
A	US, A, 5011489 (SALEM), 30 April figures 1,6, abstract	1 1991 (30.04.91),	1-14
A	EP, A1, 0501081 (CADET, PIERRE), (02.09.92)	, 2 Sept 1992	1-14
	<u>`-</u>		
	`		
Furth	er documents are listed in the continuation of Box	x C. X See patent family anne	х.
"A" docume	categories of cited documents:  ent defining the general state of the art which is not considered	T later document published after the ini date and not in conflict with the appl the principle or theory underlying the	ication but cited to understand
"E" erlier d	f particular relevance ocument but published on or after the international filing date	"X" document of particular relevance: the	claimed invention cannot be
cited to	ent which may throw doubts on priority claim(s) or which is establish the publication date of another citation or other	considered novel or cannot be considered novel or cannot be considered step when the document is taken along	e
"O" docume	reason (as specified) nst referring to an oral disclosure, use, exhibition or other	"Y" document of particular relevance: the considered to involve an inventive ste combined with one or more other suc	p when the document is
	ent published prior to the international filing date but later than trity date claimed	baing abains as a second differ to a	ne art
Date of the	e actual completion of the international search	Date of mailing of the international 0 5 -07- 1994	search report
<b>22</b> Јипе	1994		
Name and	mailing address of the ISA/	Authorized officer	
	Patent Office S-102 42 STOCKHOLM	Hans Presto	
	No. +46 8 666 02 86	Telephone No. +46 8 782 25 00	•

### INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 94/00217

Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This inte	rnational search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X	Claims Nos.: 15 because they relate to subject matter not required to be searched by this Authority, namely: Methods for treatment of the human or animal body by surgery or therapy. (PCT, Article 17(2)(a)(i), Rule 39(iv)).
2.	Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3.	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This Inte	rnational Searching Authority found multiple inventions in this international application, as follows:
1.	As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark	on Protest  The additional search fees were accompanied by the applicant's protest.  No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Form PCT/ISA/210 (patent family annex) (July 1992)

International application No.

28/05/94

PCT/SE 94/00217

US-A- 5011489 30/04/91 NONE EP-A1- 0501081 02/09/92 NONE